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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girton	S63.2H-14594-US01	6660

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EXAMINER	
PATTERSON, MARC A	
ART UNIT	**PAPER NUMBER**
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/002,521	GIRTON ET AL.	
	Examiner	Art Unit	
	MARC A. PATTERSON	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,21,22,24 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,21,22,24 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 103(a) rejection of Claims 3 and 21 – 22 as being unpatentable over Houser et al (U.S. Patent No. 6,361,559 B1), of record on page 2 of the previous Action, is withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 recites the phrase 'said dissolving medium. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections – 35 USC § 102(b)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Dillon (U.S. Patent No. 4,849,285).

Dillon discloses a material consisting essentially of an interpenetrating polymer network comprising PTFE and a solid particulate component which is incompatible with the PTFE (column 2, lines 12 - 17) and a dissolving medium in which the component is soluble (mixed into kerosene, therefore at least partially soluble before it is completely crosslinked; column 3, line 9); discrete domains of the component are therefore distributed through the PTFE and are extractable therefrom to create pores.

Claim Rejections – 35 USC § 103(a)

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 3, 21 – 22 and 29 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al (U.S. Patent No. 6,361,559 B1) in view of Clapper (U.S. Patent No. 5,744,515).

With regard to Claims 3, 21 and 29 – 30, Houser et al teach a vascular graft (bypass graft; column 7, lines 3 - 7) that is tubular (column 7, lines 23 – 25) comprising an extruded composite of materials that are selected from a group including silicone and PTFE (column 7, lines 3 - 7). It therefore would have been obvious for one of ordinary skill in the art to have provided for an

extruded composite of silicone and PTFE, therefore an interpenetrating network of silicone and PTFE, as the group disclosed by Houser et al includes silicone and PTFE. Houser et al therefore disclose an interpenetrating polymer network having discrete domains of the silicone distributed throughout the PTFE that are extractable from the PTFE to create pores, as stated in paragraph 0035 of the specification, therefore permitting tissue ingrowth; Houser et al do not disclose a PTFE that is expanded or that has a node and fibril structure; a non - expanded PTFE having no node and fibril structure is therefore disclosed by Houser et al. Houser et al fail to disclose a composite that is an interpenetrating polymer network

Clapper teaches a room – temperature vulcanizing silicone in the making of a vascular graft for the purpose of obtaining a graft that closely approximates natural vessels (column 5, lines 51 -65). One of ordinary skill in the art would therefore have recognized the advantage of providing for the silicone of Clapper in Houser et al, which comprises vascular graft, depending on the desired similarity to natural vessels of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a room – temperature vulcanizing silicone in Houser et al, therefore an interpenetrating polymer network, because the silicone is crosslinked, in order to obtain a graft that closely approximates natural vessels as taught by Clapper.

With regard to Claim 22, Houser et al fail to disclose a particle size of 5 to 100 microns. However, would therefore be obvious for one of ordinary skill to select particle size, through routine optimization, depending on the desired speed of mixing, as a composite is disclosed by Houser et al.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al (U.S. Patent No. 6,361,559 B1) in view of Clapper (U.S. Patent No. 5,744,515) and further in view of Chuter (U.S. Patent No. 6,293,969).

Houser et al and Clapper disclose a PTFE extrudate comprising extractable polymeric material in a vascular graft as discussed above. Houser et al and Clapper fail to disclose a radially distensible stent positioned axially about the extrudate.

Chuter teaches PTFE (PTFE membrane material; column 2, lines 49- 53) comprised in first and second stems (first and second stent graft components; column 2, lines 45 - 47) with one stent positioned about the other stent (the stent components are at different levels, one below the other; column 2, lines 28 - 29) for the purpose of obtaining a stent which is biologically inert (column 2, lines 49 - 53). One of ordinary skill in the art would therefore have recognized the advantage of providing for the stent of Chuter in Houser et al and Clapper, which comprises PTFE, depending on the desired inertness of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a stem, therefore radially distensible, positioned axially about the tubular extrudate in Houser et al and Clapper in order to obtain a stent which is biologically inert as taught by Chuter.

9. Claims 24 and 27 – 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freiburger et al (U.S. H1978 H).

With regard to Claims 24 and 27 – 28, Freiburger et al disclose an extrudate (column 9, lines 65 - 67) comprising an interpenetrating polymer network comprising PTFE and silicone (column 10, lines 30 - 34); Freiburger et al do not disclose a PTFE that is expanded or that has a node and fibril structure; a non - expanded PTFE having no node and fibril structure is therefore disclosed by Freiburger et al; because Freiburger et al disclose an interpenetrating polymer network, Freiburger et al disclose discrete domains of the silicone distributed throughout the PTFE that are extractable from the PTFE to create pores, as stated in paragraph 0035 of the specification, therefore permitting tissue ingrowth. Freiburger et al fail to disclose a silicone that is solid particulate. However, Freiburger et al disclose a silicone, as discussed above. It would therefore be obvious for one of ordinary skill to select a solid particulate, or liquid silicone, as solid particulate and liquid are physical states of silicone.

ANSWERS TO APPLICANT'S ARGUMENTS

10. Applicant's arguments regarding 35 U.S.C. 103(a) rejection of Claims 3 and 21 – 22 as being unpatentable over Houser et al (U.S. Patent No. 6,361,559 B1), of record in the previous Action, have been considered and have been found to be persuasive. The rejection is therefore withdrawn.

Applicant's arguments regarding the 35 U.S.C. 103(a) rejection of Claims 24 and 27 as being unpatentable over Freiburger et al (U.S. H1978 H) have not been found to be persuasive for the reasons set forth below.

Applicant argues, on page 7 of the remarks dated September 4, 2009, that silicone is not disclosed by Freiburger et al because Freiburger et al disclose polydimethyl siloxane.

However, because polydimethyl siloxane is a silicone, the argument is not persuasive.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Marc A Patterson/
Primary Examiner, Art Unit 1794